

21 Ways to Beat Zimmer

BIOMET

The TRUTH About Zimmer...

A Webcast Expose!

Welcome Biomet
East Coast Distributors & Sales Associates!

21 Ways to Beat Zimmer

Biomet Hip Marketing & Engineering Group

Photograph of Hip Group

21 Ways to Beat Zimmer

Biomet sells a hip stem every 9 minutes...
That's just in the USA

Biomet's Strengths in Hip Reconstruction

1. Widest Breadth/Scope Product Offering
2. Longest Clinical History
3. Lower-Risk Technologies
4. Strong Pipeline (*ArCom XL, Magnum, ReCap, Medallion, Porous Metal Shells, Diamond-on-Diamond, Ceramic-on-Ceramic*)
5. Favorable Market Dynamics
6. Solid, Untarnished Reputation
7. Fast-Growing Salesforce
8. Management Longevity & Industry Commitment
9. DTC Initiatives & Patient Communications

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Biomet has reported lower than expected hip growth

Biomet's Weaknesses in Hip Reconstruction

1. Surgeons want "sizzle," we have more "steak"
2. Traditional, measured approach to new product releases
3. Delayed ceramic-on-ceramic introduction
4. Surgeons are more willing to experiment vs. relying on "tried and true"
5. Late to the DTC game

21 Ways to Beat Zimmer

Zimmer remains ORTHOPEDIC ENEMY #1

Following are 21 ways you can help your surgeons:

- **Identify** Zimmer marketing propaganda
- **Clearly See** how Biomet hips are superior
- **Make Critical Evaluations** about what's best for the patient
- **Question** why Zimmer deserves their business in the first place

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Biomet's Focus For This Business Year...

1. **Long Term Clinical Success**
Forged Ti, bi-planar taper w/Porous Plasma Spray.
2. **Metal-on-Metal**
M2a 28, 32, 38mm...Magnum™ System.
3. **Freedom® Constrained Liner**
36mm Tri-mode stability.
4. **ArCom® XL**
Wear is no longer the issue.

Derek Edgar

Exhibit 34
VF 12-12-18

PLAINTIFF'S EXHIBIT
223
4:13-cv-800-SRC

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Zimmer has been dodging our best efforts for **long enough**



**21 Ways to
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#1

Extremely Limited Clinical Follow-up

"Nothing kills a good story like clinical results."

-- Austin Moore

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#1



Extremely Limited Clinical Follow-up

In business for 75 years, and Zimmer maintains only **ONE** currently marketed stem with 10-year published follow-up.

Reference: Zimmer.com, August 27, 2004.

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#1



Extremely Limited Clinical Follow-up

- Zweymuller Alloclassic Stem
(4 Papers at 10 yr avg).^{3,4,5,6}
- Spotorno CLS Stem
(3 Papers at 10 year avg).^{7,8,9}

...Yet these products were BOUGHT and their results are mostly European.

References: PubMed Search, August 28, 2004. B.21cm FST. Search terms: "Versys," "Osteo," "Medtronic," "Kinetech Hip," "Fiber Mesh."

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#2



Zimmer's Versys® Hip Has No Clinical Support

- The VerSys® Cementless Hip was studied...in a "Virtual Implantation."
- In this surgical "simulation," the Versys® was shown to "outperform" Zimmer's own Anatomic™ Hip, but only for proximal fixation.
- We are not aware of any published clinical results on the VerSys® Stem.

Reference: Institut S, et al. Comparison of the II and III inferior Acetabular hip femoral component and the VerSys Total Femoral component using virtual implantation on the OSTEONICS workstation. J Orthop Sci. 2003;8(2):232-40.

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#2



Zimmer's Versys® Hip Has No Clinical Support

- 11% revision rate @ 3-4 years with the Versys® Cemented Plus (aseptic loosening).
- Author **does not advocate** use of PMMA pre-coated components for THA.

Reference: Ezzell (AKS) Annual Meeting, 2002

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#3

**Zimmer's Technological
"Innovations" Are Hit-or-Miss**

- Zimmer Harris Precoat
- 9.5% failure at 8.4 years
 - "The mechanisms of failure of the Precoat prostheses included bone-cement loosening, focal osteolysis, stem fracture, and prosthesis-cement debonding."

References: Ong, et al. Early failure of pre coated femoral components in primary total hip arthroplasty. J Bone Joint Surg Am. 2002 May;84(A):790-92.

Coleman, J.L. Precoat Components: Another look. Orthopedics, Vol. 18, No. 8, pg. 894, September 2005.2



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#3

**Zimmer's Technological
"Innovations" Are Hit-or-Miss**

- Zimmer Poly II



Reference: Analysis of Surface Damage in Retrieved Carbon-Fiber Reinforced and Plain Polyethylene. Wright T, Rimnac C, et.al., J.B.J.S. (Am) Oct; 75(8), 1998.



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**Zimmer's Technological
"Innovations" Are Hit-or-Miss**

- Harris-Galante Cups
- Good design, overall good reported results, but consistent failures of the locking mechanism.

References: Peters, C, et al. Locking mechanism failure in the Harris-Galante porous acetabular component associated with reversed hip dislocation. J Arthroplasty. 2002 Aug;17(4):547-51.

Wang L, et al. Polyethylene liner dissociation in Harris-Galante acetabular components: a report of 7 cases. J Arthroplasty. 2002 Dec;17(12):76-81.

Doboulas, C, et al. Dissociation of polyethylene liner in uncoated Harris Galante II acetabulum: Report of 8 cases. J Arthroplasty. 2003 Mar-Apr; 18(2):139-43. (Article in German)



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#3

**HG Femoral Component
Results**

- Harris-Galante Stems
- Matt will give me text...



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#3

**Biomet's Long-Term
(10yr+) Follow-up**



- 5 Papers on the **Taperloc®**
- 4 Papers on the **Mallory-Head®**
- 1 Paper on the **Bi-Metric®**
- 1 Paper on the **Integral®**

**Simply Launching New Products
Does NOT Constitute Innovation!**



Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components," July, 2004.

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#4

**Zimmer Offers
No Product Heritage**

Bristol-Myers Squibb Company

- **Zimmer Hips in 1995**

1. Multilock®
2. Anatomic™
3. Anatomic™ HA
4. Centralalign
5. Harris™
6. Macrofit™
7. Option
8. ZCH™
9. Austin-Moore™



Reference: Orthopedic Network News, 1995

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#4



Zimmer Offers No Product Heritage

- **Zimmer Hips in 2004**
 - 1. Multilock®
 - 2. Anatomic™
 - 3. Anatomic™-HA
 - 4. Centralalign™
 - 5. Harris™
 - 6. Macrofit™
 - 7. Option™
 - 8. ZCH™
 - 9. Austin-Moore™

Reference: Zimmer.com, August 27, 2004

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#4



Zimmer Offers No Product Heritage

- **Biomet Hips in 1995**
 - 1. Mallory-Head® (1986)
 - 2. Ranawat/Burstein®
 - 3. Taperloc® (1984)
 - 4. Bimetric® (1984)
 - 5. Integral® (1988)
 - 6. Impact® (1990)

Reference: Biomet, Inc.

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#4



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#5



Zimmer Offers No Product Heritage

- **Biomet Hips in 2004**
 - 1. Mallory-Head® -- 16 years
 - 2. Ranawat/Burstein® --
 - 3. Taperloc® -- 20 years
 - 4. Bimetric® -- 20 years
 - 5. Integral® -- 16 years
 - 6. Impact® -- 15 years

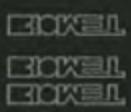
Reference: Biomet, Inc.

Zimmer Has Big Stories, But Little Support at 10+ Years

- 1. AML
- 2. Anatomic
- 3. Bi-Metric®
- 4. CLS
- 5. Integral®
- 6. Mallory/Head®

DISCONTINUED

- 7. S-ROM®
- 8. Taperloc®
- 9. TriLock (old CoCr design)
- 10. TriLock (old CoCr design)
- 11. Zweymuller/Alloclassic



Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components." July, 2004.

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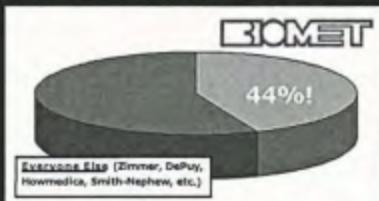
#5

44%



Zimmer Has Big Stories, But Little Support at 10+ Years

- 44% of ALL currently marketed cementless hip stems with 10yr+ results are Biomet.



Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components." July, 2004.

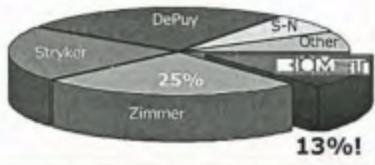
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#5



Zimmer Has Big Stories, But Little Support at 10+ Years

15% Growth for FY05



Reference: Orthopedic Research Review, Vol. 25, No. 3, July, 2004.

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#5



Zimmer Has Big Stories, But Little Support at 10+ Years

- No company can enjoy meaningful clinical results by revamping entire product lines every 7 to 10 years!
- **Clinical Results Do Matter**
 - Hospital Cost Containment
 - Legal Defensibility
 - **Patient Defensibility**
 - Credibility & Reputation
 - Selling Confidence

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#5

A CLINICAL PERFORMANCE COMPARISON OF HIP AND KNEE COMPONENTS

Primary Cementless Hip Stem Thigh Pain Rates: 10-Year Follow-Up

Component	% of Cases (approx.)
Ceramic	1
Metal-on-Metal	35
Ceramic-on-Ceramic	1
Ceramic-on-Polymer	1
Metal-on-Polymer	1
Ceramic-on-Metal	1
Total	40

Z-BEM-176

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- **Zimmer Versys® Full Coat**
 - Cobalt Chrome
 - Sintered Bead Coating
 - Distally Offloading
 - Collared
 - Bullet Tip

Zimmer Has No Design Philosophy



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Zimmer Fiber Metal Taper

- **Zimmer Versys® Fiber Metal Taper**
 - Titanium
 - Proximal Fiber Mesh Coating
 - Grit Blast Finish Distally
 - Tapered Geometry
 - Small Size Range 10-18mm

Zimmer Has No Design Philosophy



Mallory-Head® Primary Hip

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Zimmer®
Versys®
Metal Taper

Zimmer Has No Design Philosophy

Zimmer Versys® Fiber Metal Taper

1. Mullineaux BD, Bourne RB, Rorabeck CH, et al. A tapered titanium femoral stem inserted without cement in a total hip arthroplasty. *J Bone Joint Surg.* 1996;78-A(8):1214-1225. [MALLORY-HEADS_HIP](#)

2. Mallory TH. Total hip replacement in the 1990s: the procedure, the patient, the surgeon. *Contemporary Orthopaedics.* 1992;15:427-430. [MALLORY-HEADS_HIP](#)

3. Mallory TH, Head WC. A total hip replacement system: clinical experience and recommendations. *Contemporary Orthopaedics.* 1988;17(4):21-28. [MALLORY-HEADS_HIP](#)

4. Heacock W, Gardiner R, Hern S, et al. Tapered femoral components. *J Arthroplasty.* 1994;9(5):489-493. [TAPERLOC_HIP](#)

Source: [Zimmer.com](#), August 27, 2004.



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Zimmer Beaded Midcoat



Zimmer Has No Design Philosophy

- Zimmer Versys® Beaded Midcoat
 - Cobalt Chrome
 - Sintered Bead Coating (Proximal)
 - Distal Splines



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Zimmer M/L Taper



Zimmer Has No Design Philosophy

- Zimmer M/L Taper®
 - Titanium
 - Plasma Spray
 - Flat Tapered Wedge Geometry
 - 510(k) Predicate device: *Taperloc®*



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Zimmer Zweymuller



Zimmer Has No Design Philosophy

- Zimmer Zweymuller® Alloclassic
 - Titanium
 - Grit Blast
 - Tapered Flat Wedge



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#6



Zimmer Natural Hip



Zimmer Has No Design Philosophy

- Zimmer Natural® Hip
 - Titanium
 - CSTi with Hydroxyapatite Coating
 - Tapered Geometry

Sources: Helmans A.L., Friga M.E., Klaesler W., VanGorc G.C., Camargo M.P.
Cementless primary total hip arthroplasty with a tapered, proximally porous-coated titanium prosthetic:
>> a 4- to 8-year retrospective review <<

J Arthroplasty. 2000 Oct;15(7):833-8

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Zimmer Has No Design Philosophy

- Zimmer has 7 DIFFERENT Hip Systems... of which no two systems share a common philosophy.
- VerSys® System
 - Different philosophies within the same family.
 - Cobalt Chrome?
 - Titanium?
 - Sintered Beads?
 - Wire Mesh?
 - Tapered?
 - Cylindrical?
 - Splined?

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Biotmet's founders defected from Zimmer back in 1977 in order to make **BETTER PRODUCTS**



Zimmer Has No Design Philosophy

- Biomet maintains a consistent, definable, defendable design philosophy in hip engineering and design rationales.
 - Forged Ti
 - Circumferential PPS™
 - Bi-Planar taper



Not All "Plasma Sprays" Are Created Equal

- Zimmer's Plasma Spray Looks like the Biomet PPS
- It Feels like the Biomet PPS
- It is applied using a similar process to Biomet PPS

But, It is NOT Biomet's PPS.

- Very difficult process to replicate
- Pore size...pore distribution...surface Ra...mechanical interlock...bead blast levels...flame duration...operator proficiency...etc.

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#7



Not All "Plasma Sprays" Are Created Equal

- This explanted ZMR® was examined by a researcher, who concluded that INADEQUATE grit blast was the causative factor in this delamination.



Reference: Sparto, J. "Breakdown of Artificial Joint Analysis of One Zimmer ZMR hip stem." Zimmer, Inc., Indianapolis, Indiana, July 1987.



Not All "Plasma Sprays" Are Created Equal

- No records or reports exist of Biomet's PPS™ surface coating delaminating from the underlying substrate *in vivo* or even under extreme loads.



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#7



Not All "Plasma Sprays" Are Created Equal

- Don't forget that THE PLASMA SPRAY SHOWN ON THE ZMR® IS THE SAME PLASMA SPRAY coating found on the new M/L Taper® Hip.



Zimmer's M/L Taper®
Hip System



Not All "Plasma Sprays" Are Created Equal

In the words of Dr. Roger Emerson:

"[Biomet's] circumferential plasma spray coating appears to provide an effective seal of the femoral canal, preventing debris containing joint fluid from gaining access to the endosteal bone surface. The importance of this observation is that prevention of femoral osteolysis can be expected to prolong the longevity of these circumferentially coated stems".

Roger H. Emerson, Jr., M.D. et al. Effect of Circumferential Plasma Spray Plasma Coating on the Rate of Femoral Osteolysis after Total Hip Arthroplasty. *JBJS* 85 (2794) (2003)

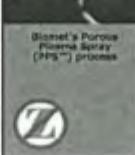
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Not All "Plasma Sprays" Are Created Equal

Zimmer has no experience and no clinical results with plasma spray.



Reference: Biomet Manufacturing, Inc. "Clinical performance of hip and knee components." July, 2004.

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#7

**Not All "Plasma Sprays"
Are Created Equal**

**Focus On
FIXATION**

Plasma Spray
& OsteoCer® HA



Y-BMT-777

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#8

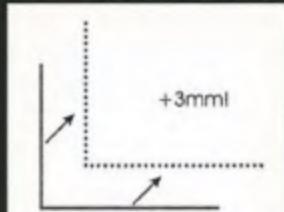
**Zimmer's M/L Taper®
Compromises a Proven Design**



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#8

**Zimmer's M/L Taper®
Compromises a Proven Design**

- M/L Taper Offset is +3mm!



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**Zimmer's M/L Taper®
Compromises a Proven Design**

- Excessive offset may irritate greater trochanteric bone and Abductor muscles, leading to painful bouts of bursitis.



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**Zimmer's M/L Taper®
Compromises a Proven Design**

ROM may be compromised if -3.5mm or other "minus" heads must be used to counteract the inherently significant lateral offset found in the M/L Taper.

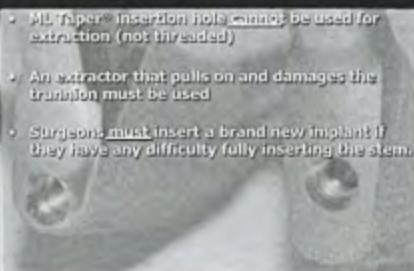
Biomet provides an 18mm neck length range vs. Zimmer's 14mm.

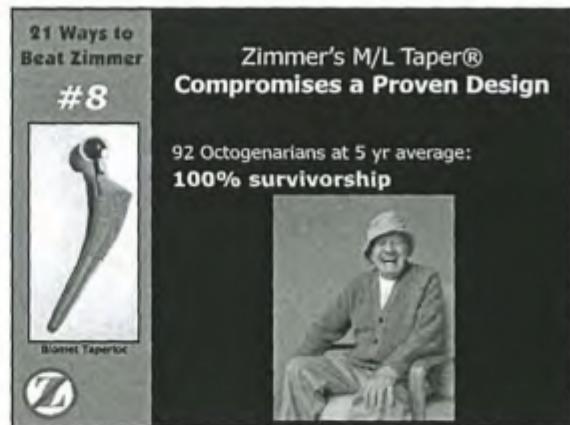


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#8

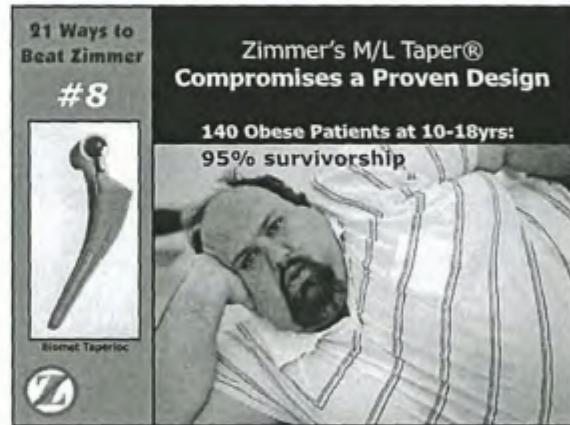
**Zimmer's M/L Taper®
Compromises a Proven Design**

- M/L Taper® insertion hole cannot be used for extraction (not threaded)
- An extractor that pulls on and damages the trunnion must be used
- Surgeons must insert a brand new implant if they have any difficulty fully inserting the stem.

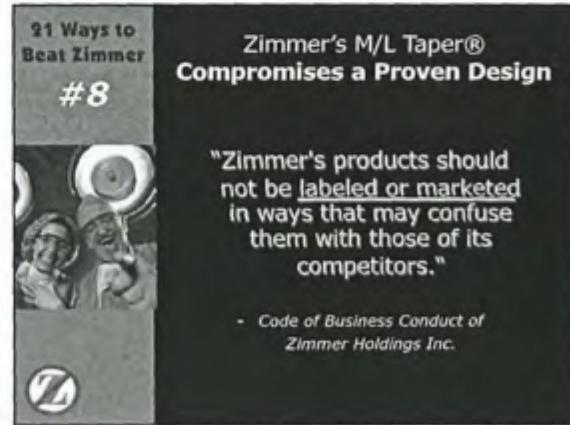




92 Octogenarians at 5 yr average:
100% survivorship



140 Obese Patients at 10-18yrs:
95% survivorship



"Zimmer's products should not be labeled or marketed in ways that may confuse them with those of its competitors."

- *Code of Business Conduct of Zimmer Holdings Inc.*

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#8

Slide to summarize the taperloc

Paper 1
Paper 2
etc



**Zimmer Is Suddenly
Committed to Metal-on-Metal
(We Think...)**

- Centerpulse's Metasul® metal-on-metal system already enjoys a prominent position on Zimmer's website.

Metasul® System



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#9

Elliot v. Elliot
January 30, 2003



**"I am not a
Metal-on-Metal
fan."**

Reference: "Zimmer, Inc. Earnings Conference Call"; Qtr 4 2002; Jan 26, 2003



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#9

Elliot v. Elliot
April 27, 2004



**"We think Metal-
on-Metal is very
strong...so we're
very excited
about Metal-on-
Metal."**

Reference: "Zimmer, Inc. Earnings Conference Call"; Qtr 1 2004; April 27, 2004



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#9

Elliot v. Elliot
January 30, 2003



**"We have done so
much looking at
[metal-on-metal],
and concluded that's
not where we want
to be."**

Reference: "Zimmer, Inc. Earnings Conference Call"; Qtr 4 2002; Jan 26, 2003



**21 Ways to
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#9

Elliot v. Elliot
April 27, 2004



**"We don't think
[metal-on-metal is]
a second place
product at all."**

Reference: "Zimmer, Inc. Earnings Conference Call"; Qtr 1 2004; April 27, 2004



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#9



**Zimmer Is Suddenly
Committed to Metal-on-Metal
(We Think...)**

"[Metal ions] are a theoretical concern that is most commonly used as a commercial argument against Metasul by companies that do not have the product."

"There is no identified increased risk of cancer with a metal-on-metal articulation that was used in the past, nor has there been any identified with Metasul..."

Reference: Zimmer.com, August 27, 2004.

**16 Ways to Sell
Metal-on-Metal**

- #8: CoCr alloy has been used for more than 60 years in millions of patients.¹
- #9: Metal ions are a byproduct of virtually every metallic implant, and will be present in the body regardless of the bearing surface chosen.²
- #10: Ceramic-on-ceramic and metal-on-polyethylene total hip replacements can release small amounts of metal ions to the body.³
- #11: The amount of metal ions released from a metal-on-metal implant is extremely low as it is measured on a parts-per-billion level.⁴
- #12: The difference between the ion release of a metal-on-metal implant and a metal-on-polyethylene hip may be as little as one to two parts-per-billion.^{5,6}
- #13: Small amounts of cobalt and chromium appear to be well tolerated by body as evidenced in multiple clinical studies conducted over the 45-year history of metal-on-metal implants, as well as in studies conducted outside of orthopedics.^{7,8}
- #14: Chromium is an essential micronutrient with a recommended daily requirement of 50 to 200 micrograms per day as established by the FDA.⁹
- #15: As with many elements, chromium exists in several atomic valence states. Chromium VI (hexavalent) and chromium III (trivalent) are the two most common. Large doses of hexavalent chromium can be toxic. No toxicity has been established from trivalent chromium.^{10,11}

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**Zimmer Is Suddenly
Committed to Metal-on-Metal
(We Think...)**

- Metasul® liners are made from conventional poly.
- Metal inserts are heat-pressed into the conventional poly.
- Metal inserts have been reported to disassociate from the poly (reference)

Zimmer's Metasul System

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Remember:

Metal Ions – A Scientific Review

Introduction

Metal-on-metal implants are used in different types of orthopaedic applications. These implants are often used in the hip and knee joints. Metal-on-metal implants are also beginning to be used in the shoulder and elbow. In fact, some hips still be used genetically engineered muscle resectioned to the bone, which is called a hemiarthroplasty. This is a procedure that replaces the femoral head with a metal ball. The patient's femur is cut and the ball is attached to the femur. The ball is usually made of cobalt-chromium-molybdenum alloy, which is a very strong material.

	Co-Cr	Poly
Wear particles	100-200	10-100
Metals released	2-5	2-5
Implant lifetime	10-20	20-30

Y-BEM-175

(You are a friggin' idiot if you haven't given this to every one of your surgeons already.)

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**16 Ways to Sell
Metal-on-Metal**

- #10: The US National Toxicology Program does not list cobalt as a recognized animal or human carcinogen.¹²
- #11: Cobalt is an essential element necessary for the formation of vitamin B₁₂, and the metabolism of proteins.¹³
- #12: Metal ions are capable of being excreted through the urine. There is a correlation between release into the body (activity) and excretion, which may avoid a local response as well as any toxic build-up on a systemic level.^{14,15}
- #13: There are no published studies linking carcinogenicity with metal-on-metal bearing and metal ion release in the 45-year history of metal-on-metal use. The *115* published scientific evidence to suggest a causal relationship between metal-on-metal implants and carcinogenicity on any level.¹⁶⁻¹⁹
- #14: Literature analysis and clinical examinations by Visek, Thakar, Brooker and others support the safe use of metal-on-metal implants and find no link to cancer.¹⁹⁻²¹
- #15: Failed metal-on-metal hips can show inflammations of the periprosthetic tissue and metal ion release in the periprosthetic tissue. Similar responses have been noted with failed ceramic-on-ceramic and polyethylene hips, or any time the periprosthetic lymph system is unable to keep up with the volume of wear particulate produced by an artificial implant.²²
- #16: Revised metal-on-metal implants have demonstrated a less severe local tissue response compared to metal-on-polyethylene hips.

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**Zimmer Is Suddenly
Committed to Metal-on-Metal
(We Think...)**

- Exposed metal edge has been associated with stem notching and metalloysis.
- The liners DO NOT provide anywhere near the 154 degrees ROM of the M2a-38™.



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More room to grow
M2a™ System!

- Shift to metal-on-metal articulations continues to be very strong.
- In latest quarter, 36% of articulations were metal-on-metal!
- 42-45% metal-metal is possible!



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#10

Zimmer's HXLP Longevity®
and Durasul® Polys Are
Showing Weaknesses

HXLP Retrieval with Surface
Damage Visible to the Naked Eye

HXLP Retrieval
with Numerous
Surface Cracks
Visible Under
Magnification

Reference: Bradford et al. BEFS Year 2004

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#10

Zimmer's HXLP Longevity®
and Durasul® Polys Are
Showing Weaknesses

- Report of early **osteolysis** with Zimmer Longevity Polyethylene.



Where is reference?



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#10

Zimmer's HXLP Longevity®
and Durasul® Polys Are
Showing Weaknesses

- Zimmer's own Ray Crowninshield questions the utility of Highly Crosslinked Poly in certain BIG HEAD applications!

"Understanding of the utility...of these bearing surfaces and their limitations is renewed importance.

Reference: HALLEY, D., GLASSMAN, A., CROWNSHIELD, R.
"Recurrent Dislocation After Revision Total Hip Replacement with a Large Prosthetic Femoral Head." THE JOURNAL OF BONE & JOINT SURGERY VOLUME 86-A NUMBER 4

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#10

Zimmer's HXLP Longevity®
and Durasul® Polys Are
Showing Weaknesses



8-Year Clinical F/U

40 % Wear Reduction

Zero Osteolysis

Head, et al. SICOT 2002



ArComXL
highly crosslinked polyethylene

- High Strength
- Low Wear
- No Oxidation
- November '04



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#10

The ArComXL Process

ArCom ICM Barstock 50 kGy Gamma Irradiation Below Melt Pre-Heat Solid State Deformation

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#10

The ArComXL Process

Low Heat Stress Relief Machining Gas Plasma or EtO Sterilization

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#11

Zimmer's Constrained Liners Are Only 2nd Best

Zimmer Trilogy Constrained Liner

- Zimmer promotes the Trilogy® Constrained insert as having 104 degrees ROM.
- According to the package insert, ROM decreases to less than 90 degrees when used with a 12/14 tapered stem (i.e. Versys®).

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#11

Zimmer's Constrained Liners Are Only 2nd Best

Zimmer Epsilon Constrained Liner

- Zimmer's other constrained liner, the Centerpulse Epsilon® Constrained Insert seems perfectly engineered for the laboratory setting.
- But 55 degrees Abduction? Higher risk of dislocation
- Crowninshield warns of excessively ABducted cups and their propensity for increased wear and lower resistance to dislocation (Harvard Hip Course Presentation, 2003).

21 Ways to Beat Zimmer

#11

Zimmer's Constrained Liners Are Only 2nd Best

- The Freedom has been implanted in over 1,000 cases since its introduction in June of 2003 and continues to be extremely successful.

21 Ways to Beat Zimmer

#11

Biomet's Constrained Liners ARE The BEST

- Freedom® Liners SELL PRIMARY STEMS
- Top FIVE Freedom™ Liner distributors booked 50% of ALL SALES during Q1

**21 Ways to
Beat Zimmer**

#12



**Zimmer's ZMR® Modular
Revision Is Weak**

- Zimmer sells more ZMR® Hips than Biomet, yet the Mallory-Head Modular Calcar has very favorable clinical results.
- Voluntary manufacturer recall
- Mechanical testing protocol based on Pre Roller-Harden technology
- Stem predicate device is actually the M-H Mod Calcar
- Roy Crowninshield published a paper in defense of poor product performance, blaming poor surgeon judgement
- NO clinical history.

**21 Ways to
Beat Zimmer**

#12



**Zimmer's ZMR® Modular
Revision Is Weak**

- **Mallory-Head® Modular Calcar**
 - Well-respected trade name
 - Proven trochanteric re-attachment option
 - myriad distal options
 - Zero Taper Breakages/5,000+ cases
 - Clinical history!

**21 Ways to
Beat Zimmer**

#13



**Secret to Modular Revision
Success: Roller Hardening**



**21 Ways to
Beat Zimmer**

#13



**Secret to Modular Revision
Success: Roller Hardening**

- Patented process developed at Biomet.
- Not developed to address weakness in non-roller hardened tapers in previous system.
- Zimmer's "Ti-Nitriding" process only hardens the SURFACE to a depth measured in microns.

**21 Ways to
Beat Zimmer**

#13



**Secret to Modular Revision
Success: Roller Hardening**

- 5,000+ implants with no reported fractures at the taper junction.
- 3 published papers documenting the clinical success of the product.

**21 Ways to
Beat Zimmer**

#13



**# Of Clinical Papers for
Currently Marketed Zimmer
Revision Stems**



21 Ways to
Beat Zimmer
#14

Tantalum Has
NO ADVANTAGE
over Titanium Alloy



- Contrary to popular rhetoric, Tantalum has NOT been shown to be any more conducive to bone formation than the proven Titanium Alloy **all** orthopedic companies use.

21 Ways to
Beat Zimmer
#14



Tantalum Has
NO ADVANTAGE
over Titanium Alloy

- Tantalum has never been used before in a load-bearing medical device application.
- High infection rates (up to 17%) in revisions mean that removal of Tantalum implants may be extremely damaging.
- Tantalum's porosity is great...unless the patient needs a revision.
- Allograft bone has been shown to perform well in revision acetabular setting.
- This is a **solution** in search of a **problem**.

21 Ways to
Beat Zimmer
#14

Tantalum Has
NO ADVANTAGE
over Titanium Alloy



- Hospitals **continue** to pay top dollar for these clinically irrelevant implants.
- Ways Tantalum is **Better** than Titanium:
 - Biocompatibility? No!
 - Cup Placement? No!
 - Joint Stability? No!
 - Ease of Operation? No!
 - Infection Control? No!
 - Fixation? No!
 - Survivorship?

21 Ways to
Beat Zimmer
#14



Tantalum Has
NO ADVANTAGE
over Titanium Alloy

- Par 5® Cup
- Healey™ Flanged Cup
- McLaughlin™ +5 Shell
- Max-Ti® Protrusio Cage
- Mallory-Head® Protrusio Cage
- Recovery™ Cage
- Biomet Tri-Flange

21 Ways to
Beat Zimmer
#15

No Clear Benefit to
Zimmer's 2-Incision
Technique



- Small scars? Yep! But...
 - Requires use of **distally-loading** stem
 - Lack of exposure limits visualization
 - Fluoro-Based visualization requires **heavy lead vests** (hot, uncomfortable)
 - Limited "Ball-Out" options
 - Extended Operating Time

With 98% survivorship at 15 yrs, what real Benefit will the patient enjoy?

Dr. Ranawat has questioned the ethical nature of the 2-incision approach.

21 Ways to
Beat Zimmer
#15



No Clear Benefit to
Zimmer's 2-Incision
Technique

Dr. Hartzband:

- "It took me **100 cases** to get real comfortable."
- "I tell my patients **not to believe the hype.**"
- "This procedure is only for surgeons doing 200-240 hips per year, **not for the surgeon doing 30 hips per year.**"

21 Ways to
Beat Zimmer
#15

**No Clear Benefit to
Zimmer's 2-Incision
Technique**

- What is the long-term efficacy of MIS techniques?
 - Limited number of short-term clinical studies
 - List studies
 - Long-term follow-up not yet possible
 - Debatable short-term benefits
 - No clinical results for Zimmer implants.
- Biomet's Microplasty™ uses clinically proven implants.



21 Ways to
Beat Zimmer
#16

Possibly **MISleading**
Patient Promotions

- "Q. Is there a difference between the replacement hip used in the *MIS* 2-Incision procedure and the one used in traditional hip replacement surgery?"
 - "A. No. The replacement hip – comprised of a stem, ball and socket – is the same high quality, **clinically proven** prosthesis that is used in traditional surgery."
- **No clinical results on the Versys® Hip**

Reference: Zimmer Holdings, Inc.
<http://www.zimmer.com/213/replacement%20procedures%20and%20options%20available>



21 Ways to
Beat Zimmer
#16

Microplasty™
minimally invasive program

- **Microplasty™ Techniques** are developed to be practical and reproducible.
- **Microplasty™ Instruments** allow for gradually working standard techniques down to less invasive techniques.
- **Microplasty™ Training** allows surgeons to gain practical MIH experience without signing an option-limiting contract
- **Rapid Recovery Program™** assists patients while promoting surgeon practices.



21 Ways to
Beat Zimmer
#16

Possibly **MISleading**
Patient Promotions

"Thousands of *MIS* hip and knee procedures have been performed. At 6 months, the **clinical outcomes are impressive and well documented**. Results indicate that the efficacy of *MIS* procedures parallels those of open procedures."¹

- 1. "Data on File at Zimmer"
Last Updated 8/19/04

Reference:
<http://www.zimmer.com/213/replacement%20procedures%20and%20options%20available>



21 Ways to
Beat Zimmer
#17

Possibly **MISleading**
Patient Promotions



Patients **may** not be told that surgeons using "MIS" instruments **may** be contractually obligated to Zimmer to use their implants for the surgery.



21 Ways to
Beat Zimmer
#17

Possibly **MISleading**
Patient Promotions

"Hip Surgery Today, Tennis Tomorrow?"

- Misleading headlines like this one from NBC Channel 5 in Chicago, are being used to promote the Zimmer MIS technique.
 - This particular article features Zimmer doctor, Mark Hartzband.
- Remember, Dr. Hartzband's comments from earlier:

"I tell my patients not to believe the hype."



21 Ways to
Beat Zimmer

#17



Possibly **MISleading**
Patient Promotions

- Few data support Zimmer's MIS approach.
- Several papers have found that a "small incision" offers no benefit! (references here)
- Waldman reports good results with small incisions...but he is using Biomet's clinically proven implants.
- Patients are far more concerned with the first 2 months, not the ensuing 20 years.

21 Ways to
Beat Zimmer

#17



Possibly **MISleading**
Patient Promotions

- Dr. Rich Berger claims that "You can do [minimally invasive surgery] with two incisions, three incisions, or ten incisions...as long as you don't cut the muscles or tendons." (Orthopedics, April 2004)
- Also, "two to ten cases" are usually sufficient to become comfortable with the 2-incision technique.
- Put other quote that says it takes a LONG time to get comfortable with min incision.
- But Dr. Hartzband says "this procedure is only for surgeons doing 200-240 hips per year."

21 Ways to
Beat Zimmer

#17



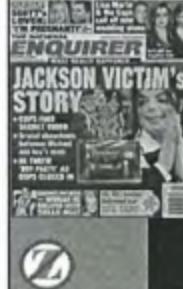
Possibly **MISleading**
Patient Promotions

- "Many clinical studies initiated by Zimmer are approved and monitored by hospital Investigational Review Boards."
 - Required by HIPPA!
 - Weak attempt to gain credibility

Reference: Zimmer Holdings, Inc.
<http://www.enquirer.com/UDepo-distribution.html#1133&Itemstate=10>

21 Ways to
Beat Zimmer

#17



Possibly **MISleading**
Patient Promotions

"We use a cementless prosthesis that grows into bone, and most leave the hospital on crutches the day of the operation."

– Richard Berger, M.D., in The National Enquirer (Dec. 9, 2003)

21 Ways to
Beat Zimmer

Summary Slide" Everything
we've talked about

- Point
- Point
- Point
- Point



Overshadowing Zimmer:
Large Articulations

- Jumbo, Hemispherical, One-Piece Cup
- Huge ROM and Stability
- Closely Replicates Patients' Natural Head Size
- FDA Clearance: Expected November '04



#18

21 Ways to
Beat Zimmer

**More Cutting Edge than Zimmer:
Hemi Resurfacing**

- Point
- Point
- Point
- Point



#21

21 Ways to
Beat Zimmer

**Mention other webcasts against
DePuy, S-N, Howmed**

- Point
- Point
- Point
- Point



#21

21 Ways to
Beat Zimmer

Thank You

- 30 minutes for question/answer
 - Ask over the phone via operator
 - Type in questions on your computer

